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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,641	02/22/2002	Patrick A. Haverkost	BSI-486US	2371

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EXAMINER

WEBB, SARAH K

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,641

Applicant(s)

HAVERKOST ET AL.

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-51 is/are pending in the application.
- 4a) Of the above claim(s) 9, 12-16, 18-29, 34-46 and 48-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10, 11, 17, 30, 32, 47, and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1,3-8,10,11,17,30,32,47, and 51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Independent claims 1 and 47 state, *"...adapted to expand into an expanded state starting with a proximal region of the device...as the anterograde sheath is advanced distally."* This phrase renders the claims indefinite, because the elected species is not disclosed as being capable of performing in this manner. Since the anterograde portion only covers a portion of the stent that is distal to the proximal end, the anterograde portion can only deploy the distal portion of the stent. As Figure 2 of the disclosure clearly illustrates, distal movement of the anterograde sheath (104) would not deploy the proximal end (131) of the stent (130). The proximal end of the stent is actually deployed by proximal retraction of the retrograde sheath.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1,3-8,10,11,17,30,32,47, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,201,757 (Heyn et al) in view of US Patent No. 6,042,589 (Marianne).

Heyn discloses a stent introducer (Figures 2 and 4) that includes a shaft (78) with a distal tip (84), inner sheath (100), stent (106), anterograde sheath (82) attached to the distal tip (84), and a retrograde sheath (94). The anterograde sheath (30) and the retrograde sheath (20) are moveable between the

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positions of abutting one another and being laterally spaced from one another. The anterograde sheath (30) is axially moveable in a distal direction by distally moving the shaft (44), since the sheath (30) is connected to the shaft (44) by way of distal tip (40) (column 5, lines 30-35 and column 6, lines 27-29).

Heyn also includes an anchoring means in the form of detent (104) in the retrograde portion for preventing axial movement of the stent. Regarding claims 10 and 11, a "radial spacer" attached proximal to the distal tip provides space between the inner sheath (100) and the anterograde sheath (82).

Heyn includes all the limitations of the claimed invention, but fails to form the anchoring means as a balloon. Marianne discloses a stent (7) introducer with a retracting sheath (16) and a proximal anchoring means in the form of a balloon (20). Marianne teaches that a balloon positioned in the retrograde portion of the stent provides better control of the stent during placement. The balloon prevents axial movement of the stent during retraction of the sheath for deployment. It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the anchoring detent of Heyn with a balloon, as taught by Marianne, in order to provide better control of the stent during the placement procedure. The balloon is also capable of anchoring the stent in the body lumen, as Marianne explains that the balloon can be used to reposition the stent in the body lumen (column 3, line 35). Figures 4 and 5 clearly illustrate the balloon anchoring the stent against the lumen of a vessel.

Marianne further teaches that an inner sheath mounted over the shaft (8) can define an inflation lumen (22) for the balloon (20) (column 4, line 10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching of Marianne to adapt the inner sheath of Heyn to define an inflation lumen for the balloon of the device, as modified above.

Regarding claims 7, 8, and 17: The modified Heyn device fails to include a medial sheath. In Figure 13 of Heyn, a medial sheath (246) is located between the inner and retrograde sheaths. It

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terminates proximally to the stent. Heyn teaches that such a "medial sheath" (246) can be provided as a proximal stop for the stent (column 11, line 27) so that it won't travel into the proximal region of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a medial sheath in the modified Heyn device in order to prevent the stent from traveling proximally into the device.

3. Claims 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyn in view of US Patent No. 5, 445, 646 (Euteneuer).

Heyn includes all the limitations of claims 31 and 33, except for making the antegrade sheath cover more of the stent than the retrograde sheath and overlapping the two sheaths. Euteneuer discloses a stent introducer in Figure 2 that is similar to Heyn. The device includes both a retrograde (14) and an antegrade (16) sheath. The antegrade sheath covers a greater portion of the stent than the retrograde sheath in order to provide an overlapping region. Euteneuer explains that the overlap forms a seal (column 6, lines 47-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to lengthen the antegrade sheath of Heyn so that it overlaps the retrograde sheath, as Euteneuer teaches that this structure forms a seal around the stent.

Response to Arguments

4. Applicant's arguments filed 8/25/04 regarding the 103 rejections under Heyn and Marianne have been fully considered but they are not persuasive. Applicant argues that neither Heyn alone nor Marianne alone is capable of performing the functions set forth in claims 1 and 47. The combination of Heyn and Marianne is used to reject these claims. As modified, Heyn includes a balloon in the proximal region of the stent, which corresponds to the retrograde sheath (20). The antegrade sheath (30) is axially moveable in

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a distal direction by distally moving the shaft (44), since the sheath (30) is connected to the shaft (44) by way of distal tip (40) (column 5, lines 30-35 and column 6, lines 27-29). The modified Heyn device includes all the structural limitations of the claims and is quite similar to the elected species in Figure 2.

The phrase "wherein the distal movement of the anterograde portion allows expansion of the endoluminal device from the compressed state to an expanded state starting with a proximal region of the device and progressing toward the device distal end" is only a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The modified Heyn device includes all the structural limitations of the claimed invention. The device is also capable of being manipulated in the same manner as the elected species in Figure 2 of the application, in which the retrograde sheath is actually retracted first to deploy the proximal end of the stent, the anchoring balloon is inflated, and the anterograde sheath is lastly moved distally to deploy the remaining portion of the stent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
3/3/05

SKW

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER